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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,340	05/15/2001	Thomas J. Hosted JR.	IN01164K	9296

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

SCHLAPKOHL, WALTER

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,340	HOSTED ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	<i>Wf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 3/7/2006.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,6,8-18,21 and 24-26 is/are pending in the application.

 4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,6,8-18,21 and 24-26 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 15 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

 a) ☐ All b) ☐ Some * c) ☐ None of:

 1. ☐ Certified copies of the priority documents have been received.

 2. ☐ Certified copies of the priority documents have been received in Application No. _____.

 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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DETAILED ACTION

Receipt is acknowledged of the papers filed 3/7/2006. Claims 1, 6, 8-18, 21 and 24-26 are pending and under examination in the instant application. The finality of the previous Office action has been withdrawn.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: specifically, Figures 4 and 5 are missing reference labels "a-d" as mentioned in the figure descriptions. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office

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action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 18 and 25 are objected to because of the following informalities: claim 18 recites "[a] method for transforming an actinomycete with a vector of claim 8 comprising the step of contacting said actinomycete with said vector under conditions permitting transformation of said actinomycete" in lines 1-6. Claim 18 should instead recite "[a] method for transforming an actinomycete with ~~[[a]]~~ the vector of claim 8 comprising the step of contacting said actinomycete with said vector under conditions permitting transformation of said actinomycete."

Similarly, claim 25 recites "[a] method for transforming an actinomycete with a vector of claim 6 comprising the step of contacting said actinomycete with said vector under conditions permitting transformation of said actinomycete" in lines 1-4. Claim 25 should recite "[a] method for transforming an actinomycete with ~~[[a]]~~ the vector of claim 6 comprising the step of contacting said actinomycete with said vector under conditions permitting transformation of said actinomycete" in lines 1-6.

Appropriate correction is required.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18 and 21 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1, 4 and 9 of US Patent Application No. 11/021,825. Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but

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an examined application claim is not patentably distinct from the reference claims(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). The MPEP states, at §804, that

[t]he specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCOA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-2, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

With respect to instant claims 18 and 21, the instant claim in each instance is more narrowly drawn than the copending claims, i.e., the instant claims are drawn to a method of transforming an actinomycete with a vector comprising an integrase, an excisionase and an attP site while the copending claims are drawn to a method for making an integrase by

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transforming a host cell with a polynucleotide encoding an integrase. However, the portions of US Patent Application 11/021,825 and US Patent Application 09/758,759, incorporated therein by reference, that supports each of claims 1, 4 and 9 defines the patented invention as including embodiments which possess each of the narrower limitations of the instant claims. Thus, the method of instant claims 18 and 21 are not patentably distinct from that of copending claims 1, 4 and 9.

Claim Rejections - 35 U.S.C. §102

Claims 1, 6, 8-18, 21 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Hosted et al (US2004/0101832 A1; see the entire application) or Hosted et al (U.S. Patent No. 6,861,513 B2; see the entire reference). This rejection is maintained for reasons of record in the office action mailed 5/6/2005, which grounds for rejection are repeated below.

The applied reference has a common assignee and common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 USC 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference

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was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

U.S. Patent 6,861,513 and U.S. 2004/0101832 are derived from the same application (Serial No. 09/758,759). All of the citations presented below are taken from the published application.

Hosted et al teach nucleic acids and vectors encoding an *M. carbonacea*-specific integrase gene and the cognate integration site (e.g. Figures 9A & 9B; paragraphs 0028, 0033, 0151; SEQ ID NO:176). Thus, Hosted et al teach nucleic acids, vectors and host cells that meet the claim limitations.

Response to Arguments

Applicant argues that the rejection of claims 1, 6, 8-18, 21 and 24-26 under 35 U.S.C. §102(e) should be withdrawn because Hosted et al is not a prior art reference with respect to the instant application because the *Xis* gene sequence (SEQ ID NO:2) and the *M. carbonacea* attP/attB region (SEQ ID NO:6) were discovered before the 12 January 2000 priority date of the cited references. As evidence of this point Applicant has submitted a declaration under 37 CFR § 1.131 ("Hosted Declaration").

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Applicant's arguments are respectfully found unpersuasive for the reasons set forth below.

Response to Amendment

The declaration filed on 3/7/2006 under 37 CFR 1.131 has been considered but is ineffective. Although Applicant has included all the inventors of the instant application on the declaration, the affidavit or declaration under 37 CFR 1.131 remains ineffective because it does not contain an allegation that the acts relied upon to establish the date prior to the reference or activity were carried out in this country or in a NAFTA country or WTO member country (see MPEP 715.07(c) and 35 U.S.C. 104).

Examiner has, however, considered the substance of the declaration filed on 3/7/2006 under 37 CFR 1.131 and found that, should the above allegation be included, the declaration would be sufficient to overcome the Hosted et al reference.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the

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Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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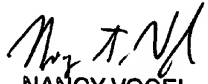
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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

March 29, 2006


NANCY VOGEL
PRIMARY EXAMINER